

FIG. 2

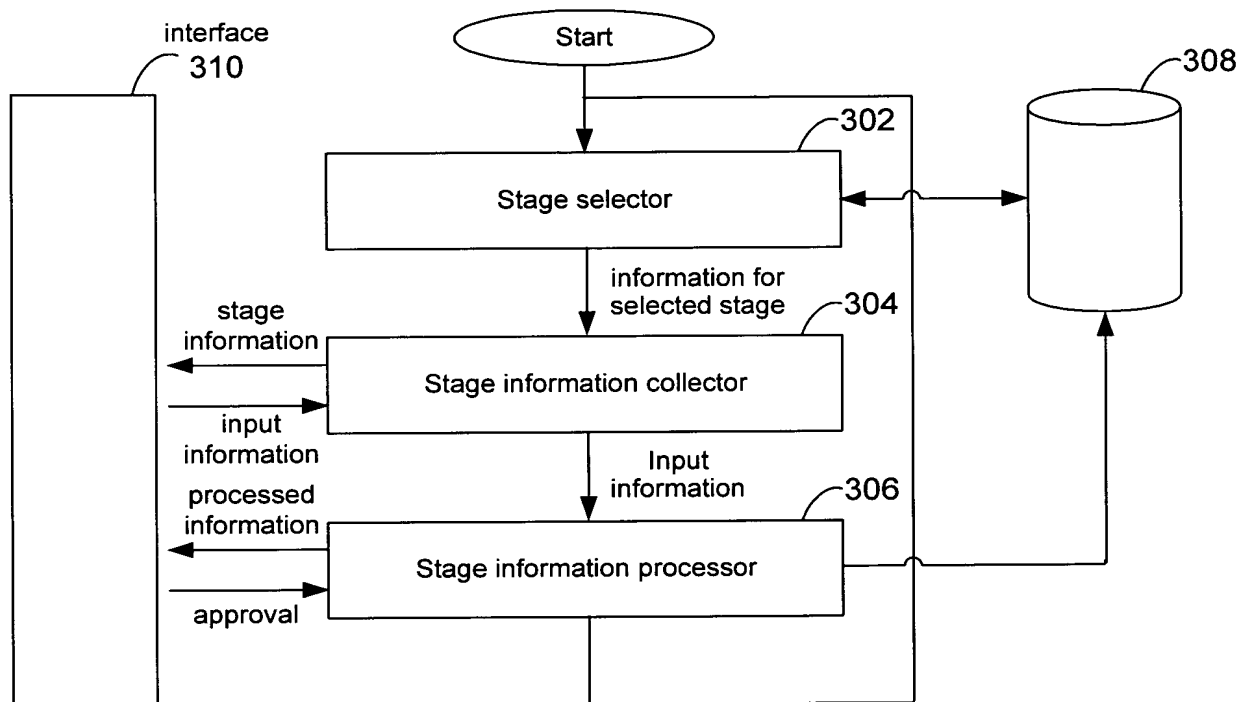
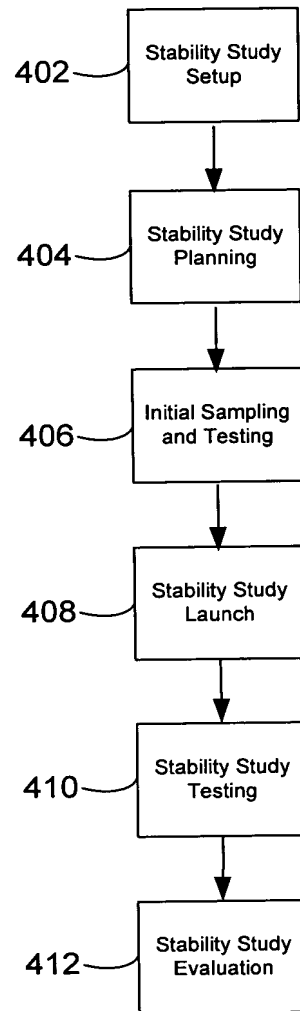


FIG. 3

**FIG. 4**



Test Interval Plan

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Set Up Test Interval

Test Interval Plan

Test Interval Plan Accelerated ☒ Overlay

Description Accelerated storage period

Base Test Interval Plan Baseline All monthly intervals within 36 months

Duration 36 Months

Simulation Start Date 01-MAY-2003 00:00:00

Frequency 1 Months

Duration 3 Years

Period Name Prefix Month

OK

Cancel

Interval Period

Time Interval From Start

From Base

Period	Years	Months	Weeks	Days	Hours	Simulated Date	Exclude
Month-Pull-1		1				01-JUN-2003 00:00:00	<input checked="" type="checkbox"/>
Month-Pull-2		2				01-JUL-2003 00:00:00	<input checked="" type="checkbox"/>
Month-Pull-3		3				01-AUG-2003 00:00:00	<input checked="" type="checkbox"/>
Month-Pull-4		4				01-SEP-2003 00:00:00	<input checked="" type="checkbox"/>
Month-Pull-5		5				01-OCT-2003 00:00:00	<input checked="" type="checkbox"/>
Month-Pull-6		6				01-NOV-2003 00:00:00	<input checked="" type="checkbox"/>
Month-Pull-7		7				01-DEC-2003 00:00:00	<input checked="" type="checkbox"/>

Include All

Exclude All

Fig. 5A



Overlay Monitoring Specification

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Specifications

Spec **30/60** Version **100** Status **Approved for General Use**

Description **Storage conditions: 30 deg C +/- 2 deg C and 60% RH +/- 5% RH**

Spec Type **Monitoring** ☒ Overlay Base Spec **25/60** Version **100**

Item Grade

Owner Organization **PR1** Owner **PROCESS_OPS**

Targets Actions Formatting Planning

Seq	Class	Test	Method	From Base	Exclude	Modify	Target	Minimum	Maximum
10		Temp-Fridge	RH-Fridg	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	30.00	28.00	32.00
20		RH-Fridge	RH-Fridg	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60.00	55.00	65.00
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			

Validity Rules

Fig. 5B

Storage Condition Plan

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Storage Condition Plan **Drug Storage**

Description **Refrigerated storage conditions for Drug substances**

Base Test Interval Plan **Baseline**

Duration **36 Months** [ok]

Storage Details 564

Storage Spec Name	Storage Spec Version	Resource	Whse	Location	Test Interval Plan	Duration
25/60	100		PR1	1-1-1	Long Term	36 Months
30/60	100		PR1	2-1-1	Intermediate	36 Months
40/75	100		PR1	3-1-1	Accelerated	36 Months

Fig. 5C

570 ~

Storage Packages							
Name	Item	Description	Formula	Version	Qty	UOM	
100-Bag	100LB BAG	100lb bag			100	Lbs	
200-Bag	200LB BAG	200lb bag			200	Lbs	
Aluminum Can	6001	Home Style Root Beer			2	KGM	
Bottle BOM			8910	1	24.55	KGM	
Carton	9903	Carton			18	OZ	
Plastic Bottle	8901	100cc White Round Pl			10	ALB	
Polyethylene	ZEPKGS	R&D Pkg 01			5.5	LBS	

572

Fig. 5D

Item Specification

580

Specifications

Spec: 8301 Version: 103 Status: Approved for General Use

Description: Bulk WIP inspection - without pH test

Spec Type: Item ☒ Overlay Base Spec: 8301 Version: 101

Item: 8301 Bulk Drug Substance Grade:

Owner Organization: PR1 Owner: PROCESS_OPS

Targets Actions Formatting Planning

Seq	Class	Test	Method	From Base	Exclude	Modify	Target	Minimum	Maximum	Unit
10		Potency	DEFAULT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	75.00000	50.00000	100.00000	PU
20		Coloration	D6543.02	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Medium			
30		Opacity	ASTM4321	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Transpar	Opaque	
40		Purity	ISO123-45	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	99.50000	80.00000	100.00000	%
50		pH	D9876.01	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	7.00	4.00	10.00	PH
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

Validity Rules

Fig. 5E

Stability Study

600

Stability Study

Study

PR1

000091

Status

In Progress

Description

Stability of Drug Tablets per protocol 55.101.68

Storage Condition Plan

Drug Storage

Item

8301

Bulk Drug Substance

Master Item Spec

8301

Version

101

Lab Organization

LAB

Default Lab

Owner

PROCESS OPS

Notification Lead Time

2

Days

Testing Grace Period

2

Days

Variant

Material Sources

2

Storage Conditions

3

Packages

1

Count

6

Dates

Start

End

Scheduled

05-JUN-2003 17:00:00

05-JUN-2006 17:00:00

Revised

Actual

05-JUN-2003 14:59:37

Recommendations

Shelf Life

Storage Spec

Version

Variants

Material Sources

Actions

Window

Help

Mark for Purge

Edit Text

Change Status

View Master Item Specification

View Storage Condition Plan

Calculate Sample Quantity

Select Initial Sample Group

Record Details

Fig. 6A

620

Study Variants

Variants

630

Variant - 1

Study **PR1** **000091** Status **In Progress**
Item **8301** **Bulk Drug Substance** Variant Count **6**

Variant | Material Source | Storage Condition | Package

632

Num	Default Spec	Version	Start Date	End Date	Samples Per Time Point	Retained Sample
1	8301	101	05-JUN-2003 14		1	0
2	8301	101	05-JUN-2003 14		1	0
3	8301	101	05-JUN-2003 14		1	0
4	8301	101	05-JUN-2003 14		1	0
5	8301	101	05-JUN-2003 14		1	0
6	8301	101	05-JUN-2003 14		1	0

Item Spec | Storage Spec | Samples | Time Points

Actions Window Help
Edit Text
View Storage Spec Samples
Modify Storage Condition
View Storage History
Assign Sample To Time Points
Generate Sample Labels

Fig. 6C

Time Points

Variant, Time Point - 1, Month-Pull-1

702

Time Interval	Spec Name	Version	Scheduled date	Actual Date	Samples Per Time Point	Disposition
Month-Pull-1	8301	101	05-JUL-2003 14:36		1	Accept
Month-Pull-6	8301	103	05-DEC-2003 14:36		1	Retain
Month-Pull-12	8301	101	05-JUN-2004 14:36		1	Retain
Month-Pull-18	8301	103	05-DEC-2004 14:36		1	Retain
Month-Pull-24	8301	101	05-JUN-2005 14:36		1	Retain
Month-Pull-30	8301	103	05-DEC-2005 14:36		1	Retain

704 706

Item Spec Samples

Actions Window Help
 Edit Text
 View Storage Spec Samples
 Modify Storage Condition
 View Storage History
 Assign Sample To Time Points
 Generate Sample Labels

Replace a Variant Storage Condition

720

Change Storage

722

From Storage Condition

Resource	Instance	Whse	Location	Start Date	End Date
		PR1	1	12-JUN-2003	22-JUL-2003

722

To Storage Condition

Resource	Instance	Whse	Location	Start Date
		PR1	2	22-JUL-2003

Cancel OK

Fig. 7B

Completed Stability Study

800

Stability Study

Study **PR1** 0012 Status **Completed**

Description **MANTEST**

Storage Condition Plan **FILLUPEVERYTHING**

Item **10002200** **Orange Juice 6X1L**

Master Item Spec **B** Version **1**

Lab Organization **LAB** **Default Lab** Owner **MAGUPTA**

Notification Lead Time **804** Testing Grace Period

802

Variant

Material Sources **1**

Storage Conditions **1**

Packages **1**

Count **6**

Dates

	Start	End
Scheduled	22-APR-2003 00:00:00	30-MAY-2004 01:00:00
Revised		
Actual		20-MAY-2003 09:14:13

806

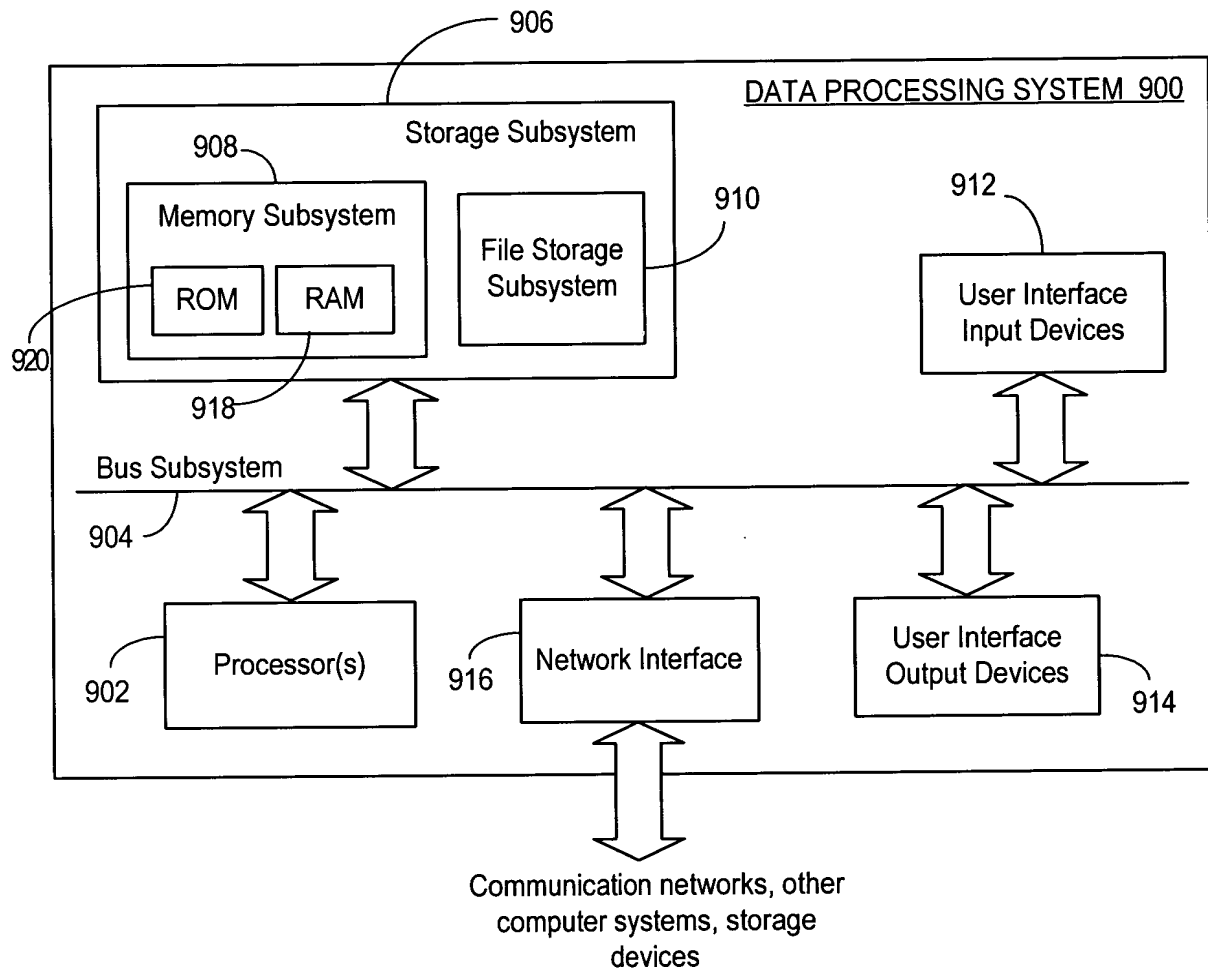
Recommendations

Shelf Life **2** **Years**

Storage Spec **MARCHMONITOR** Version **1**

Variants **Material Sources**

Fig. 8

**FIG. 9**